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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/380,857	01/30/95	HARDY	B 22671

EXAMINER
JOHNSON, N

18M1/0528

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ART UNIT	PAPER NUMBER
1806	

DATE MAILED: 05/28/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on 2.27.97

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 19-27 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☒ Claim(s) 19-23 is/are allowed.
☒ Claim(s) 24-27 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 12
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

–SEE OFFICE ACTION ON THE FOLLOWING PAGES–

1. Claims 19, 20, 24 and 26 have been amended.

Claims 19-27 are pending.

2. The objection to the drawings is maintained. The subfigures of Figures 1-4 must be separately labeled. The applicant refers to copies of proposed amended Figure 4, attached to the response of February 22, 1997. No such amended Figure was found in the file.

3. The objections to the disclosure are withdrawn.

4. It is noted that Enclosures A and B were not found attached to the Declaration of Dr. Britta Hardy.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The rejection of claims 19-27 under 35 U.S.C. § 112, first paragraph, as the specification lacks complete deposit information for the deposit of the hybridoma cell line CNCM Accession No. I-1397 is withdrawn in the Declaration of Dr.

Fischman and a copy of the official receipt from the CNCM depository.

7. The rejection of 19-27 under 35 U.S.C. § 112, first paragraph, as not enabled for claims broadly drawn to "a monoclonal antibody which binds to an antigen which the antibody under (i) binds" is withdrawn in view of the amendments to the claims

8. The rejection of claims 24-27 under 35 U.S.C. § 112, first paragraph, as not enabled for claims drawn to the in vivo treatment of human tumors by the administration of monoclonal antibodies is maintained.

A Declaration by Dr. Britta Hardy has been provided that documents anti-tumor activity of the "BAT mAb" monoclonal antibody in nude mice carrying xenografts of the human HT-29 colon carcinoma tumor cell line and in SCID mice engrafted with human lymphocytes and inoculated with human SK-28 melanoma tumor cells. The declaration also demonstrates the in vitro stimulatory effect of BAT mAb on human peripheral blood

lymphocytes that were pre-incubated on monolayers of HT-28 human colon carcinoma tumor cells.

Clarification is requested. The claimed method is drawn to the use of the monoclonal antibody secreted by the hybridoma cell line CNCM Accession No. I-1397, which is called the BAT-1 monoclonal antibody (see specification p.7, lines 11-17). The declaration gives results obtained with the "BAT" monoclonal antibody. Given that in addition to the BAT-1 antibody the specification also discloses the BAT-2, BAT-4 and BAT-5 monoclonal antibodies (see Description of Figure 1, p.9), the question is raised as to whether the results set forth in the declaration were obtained with the same BAT-1 antibody of the claimed cancer treatment method.

If the "BAT" monoclonal antibody of the declaration is not the very same antibody as the "BAT-1" monoclonal, the declaration provides results irrelevant to the question at hand, and the rejection under 35 U.S.C. § 112, first paragraph, is maintained.

Further, assuming the identity of the "BAT" and the "BAT-1" monoclonal antibodies, the rejection under 35 U.S.C. § 112, first paragraph, is maintained. While the declaration documents the anti-tumor activity of the monoclonal antibody against the human

HT-29 colon carcinoma tumor cell line in the nude mouse and the human SK-28 melanoma tumor cell line in the SCID mice, both are human xenografts into the mouse system. Hird and Epenetos notes that "nude mice containing human tumor xenografts are the most widely used animal model. The data obtained from mouse studies are useful, but cannot be directly translated to apply to the human situation" (see p.185). However, the record contains no evidence that such model systems are widely accepted by those of skill in the art to be predictive of the effectiveness of the claimed method in the treatment of human tumors and cancer.

9. The rejection of claims 20 and 24-27 under 35 U.S.C. § 112, second paragraph, is withdrawn in view of the amendments to the claims.

10. The rejection of claims 19, 21-22, 24 and 26 under 35 U.S.C. § 102(b) as anticipated by Ledbetter (U.S. Patent No. 5,182,368, filed May 24, 1991) is withdrawn in view of the amendment to the claims.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy A. Johnson, Ph.D. whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday-Friday from 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax number for the group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nancy A. Johnson, Ph.D.
May 23, 1997

LILA FEISEE
SUPERVISORY PATENT EXAMINER
GROUP 1800